

EXHIBIT B



March 24, 2023

Evan Masingill
Chief Executive Officer
GenBioPro, Inc.
3651 Lindell Road
Suite D1041
Las Vegas, NV 89103

Mr. Masingill:

I write in acknowledgment of your March 1, 2023, letter addressed to the Commissioner of Food and Drugs, requesting “confirmation that any withdrawal of the approval of [GenBioPro, Inc.’s] abbreviated new drug application (‘ANDA’) for mifepristone—whether by court order or otherwise—will follow all applicable procedures afforded by law and regulation to GBP as the ANDA holder and that FDA will permit GBP to continue marketing and selling mifepristone until those procedures have been completed,” including any applicable requirements of 21 U.S.C. § 355(e). Your letter has been referred to the Center for Drug Evaluation and Research for this response.

In their Complaint in *Alliance for Hippocratic Medicine v. FDA*, the Plaintiffs have asked the Court to issue “a preliminary and permanent injunction ordering Defendants to withdraw mifepristone . . . as [an] FDA-approved chemical abortion drug[.]” According to the transcript of the March 15, 2023 hearing in this matter, the Plaintiffs have argued that “the Court, on its own accord, can order the FDA to withdraw or suspend the approval of the drug,” rather than “order the FDA to begin a suspension or withdrawal” process under 21 U.S.C. § 355(e). Arg’t Tr. at 145–46. The Court stated that it plans to “issue an order and opinion as soon as possible.” *Id.* at 155. FDA will, of course, need to review the Court’s opinion and order before determining what steps may be necessary to comply with it.

Sincerely,

Patrizia Cavazzoni, MD
Director, Center for Drug Evaluation and Research
Food and Drug Administration



CC:

The Honorable Robert M. Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Hon. Xavier Becerra
Secretary
Department of Health and Human Services
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